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ORIGINAL ARTICLE

External Quality Assessment for Severe Acute Respiratory Syndrome Coronavirus 2 RNA Detection in Chongqing, China

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SUMMARY

Background: **Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) poses a huge threat to public health. Therefore, clinical laboratories must have the ability to detect SARS-CoV-2 RNA. With the enhanced detection in Chongqing, many laboratories rapidly implemented assays for the molecular detection of SARS-CoV-2 based on real-time reverse transcription polymerase chain reaction (rRT-PCR) assays. This study aimed to improve the detection capabilities of clinical laboratories by evaluating their performance for SARS-CoV-2 RNA detection through the external quality assessment (EQA) programs of 2020 in Chongqing to contribute to the prevention of this epidemic.**

Methods: **The EQA panels consist of eight positive samples with concentrations within 2.7 - 5.0 $\log_{10}$ copies/mL quantified by digital PCR and two negative samples with other human coronaviruses clinically validated by four commercial assays. All 21 samples from four rounds were distributed to the participating laboratories through cold-chain transportation. Depending on the results from each sample, laboratories were asked to use one or two assays to detect SARS-CoV-2 RNA. Test results and raw data were also required. All data were evaluated, and the testing performance of commercial assays was compared. For the rounds, all laboratories used commercial assays.**

Results: **Four rounds of EQA programs were performed, and the percent agreements of participants were 97.5% (39/40), 97.5% (39/40), 98.9% (88/89), 100.0% (131/131). Only three false negative results and one false positive result were obtained. Statistical significance in the Ct values of the ORF region and N region of SARS-CoV-2-RNA was found by using one-step, one-step concentration, and magnetic bead methods ($p < 0.05$). The Ct values of the ORF region of SARS-CoV-2-RNA in P5 and P6 were significantly different in the different batches of reagent A ($p < 0.05$). The ORF region of SARS-CoV-2-RNA was not detected in a batch of reagent B.**

Conclusions: **The majority of laboratories in Chongqing have reliable diagnostic ability for SARS-CoV-2 detection. Our data emphasized the importance of EQA for monitoring the performance of clinical laboratories. However, clinical laboratories must first effectively evaluate the performance of reagents prior to their use.**

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Supplementary Tables and Figures

Table S1. The uniformity test results of positive samples of EAQ panels.

Sample No.	Target CT value	Actual CT value (mean ± SD)	F value	p
P1	34.2	34.4 ± 0.34	1.62	> 0.05
P2	35.0	34.9 ± 0.23	1.49	> 0.05
P3	36.2	36.0 ± 0.11	1.32	> 0.05
P4	30.3	30.5 ± 0.19	1.41	> 0.05
P5	30.8	31.0 ± 0.25	1.55	> 0.05
P6	33.3	33.3 ± 0.38	1.36	> 0.05
P7	36.8	36.5 ± 0.16	1.62	> 0.05
P8	38.0	38.0 ± 0.21	1.44	> 0.05

Table S2. The stability test results of positive samples of EAQ panels.

Sample No.	4°C (mean ± SD)	-20°C (mean ± SD)	T value	p
P1	34.7 ± 0.52	33.9 ± 0.33	2.00	> 0.05
P2	35.3 ± 0.34	35.1 ± 0.17	1.87	> 0.05
P3	36.0 ± 0.19	36.1 ± 0.26	1.56	> 0.05
P4	30.5 ± 0.22	30.8 ± 0.25	1.49	> 0.05
P5	31.0 ± 0.28	30.9 ± 0.15	2.15	> 0.05
P6	33.6 ± 0.37	33.7 ± 0.32	1.96	> 0.05
P7	36.5 ± 0.53	36.6 ± 0.27	2.01	> 0.05
P8	38.5 ± 0.41	38.6 ± 0.11	1.35	> 0.05

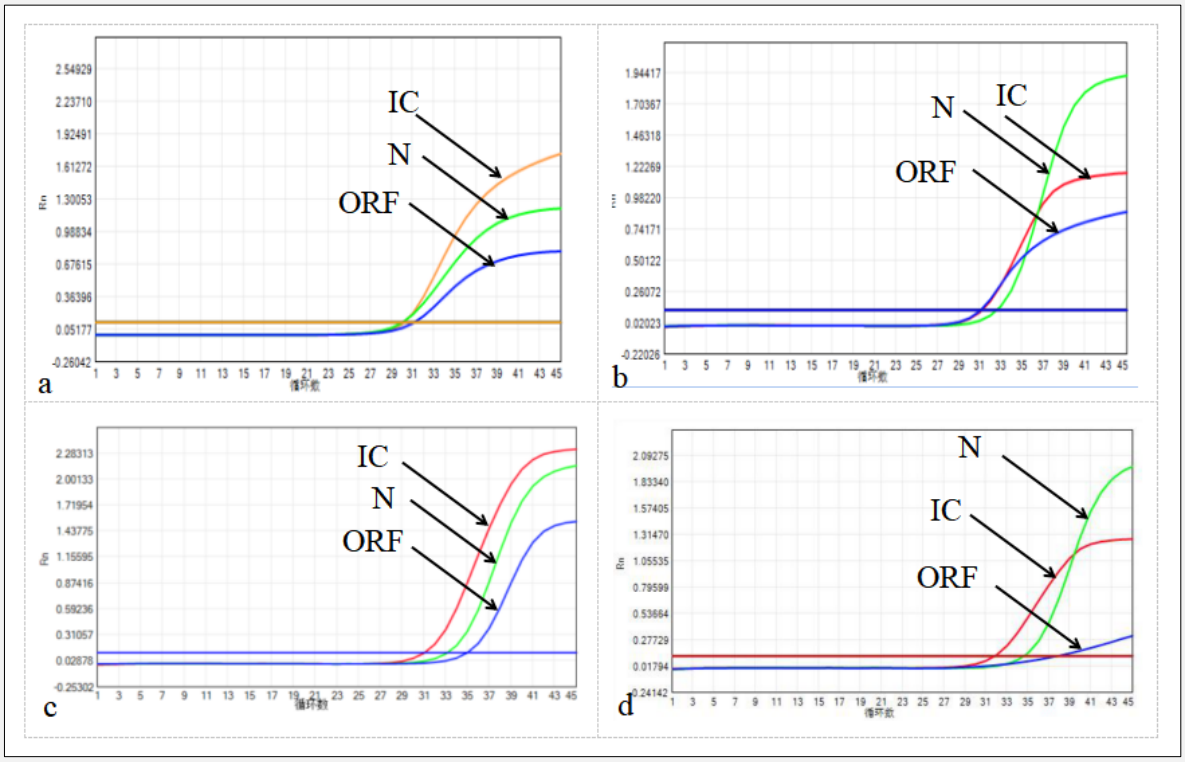

Figure S1. The test results of P4 of EAQ panels by four detection reagents.

Note:
a, Daan, Daan Gene Co., Ltd of Sun Y at-sen University, Guangzhou, China.
b, Sansure, Sansure Biotech Inc, Changsha, China.
c, Bioperfectus, Bioperfectus Technologies Co., Ltd, Jiangsu, China.
d, XABT, Beijing Applied Biological Technologies Co., Ltd., Beijing, China.
Abbreviations: IC - inner control, N - N region of SARS-COV-2, ORF - ORF1ab region of SARS-COV-2.